



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Vacuum Tray Dryer.

2.0 SCOPE:

2.1 The procedure is applicable for the Cleaning and Operation of Vacuum Tray Dryer in production department.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation
3.2 Production Officer/ Executive : Checking of Cleaning and Operation
3.3 IPQA Person : Line Clearance, On line Process Confirmation.
3.4 Head Production : SOP Compliance

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING:

Change over from one batch to next batch of the same product, same potency and of similar product with ascending potency provided the colour is same.

- 5.1.1 Ensure that power supply is turned "OFF".
5.1.2 Remove and destroy "UNDER CLEANING" label.
5.1.3 Enter the cleaning start time in equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").
5.1.4 Remove all trays from the drier and keep on SS pallet.
5.1.5 Drain the accumulated water from the "Moisture content Reservoir".
5.1.6 Remove the adhered materials from the trays by using dry lint free cloth.
5.1.7 Clean all the internal parts such as convection plate and inner SS walls of the equipment with a dry lint free cloth.
5.1.8 If the same product is processed for more than a week, then follow the procedure of cleaning as



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

followed during product change over as per Type B cleaning.

- 5.1.9 Affix duly filled and signed “CLEANED” label on the equipment.
- 5.1.10 Record the cleaning completion time in the equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.2 “TYPE B” CLEANING

During changeover of product with different actives / colour / descending potency or after maintenance of contact parts.

- 5.2.1 Follow the procedure from step 5.1.1 to 5.1.4.
- 5.2.2 Cover the electric panel with the polybags.
- 5.2.3 Clean the trays with 40 to 45 liters of purified water by using nylon scrubber.
- 5.2.4 Wash the trays with 35 to 40 liters of purified water.
- 5.2.5 Rinse the trays with 15 to 20 liters of purified water
- 5.2.6 Clean the internal parts like convection plate and inner SS walls by using CIP pump and Finally rinse the Vacuum Tray Dryer with the 50-60 liters of purified water and remove the water droplets through compressed air.
- 5.2.7 Run the vacuum tray dryer for 10 minutes to remove internal moisture.
- 5.2.8 Clean outer parts such as body, vacuum releasing chamber, hot water supply and return pipe and door of the equipment with a lint free cloth dipped in purified water.
- 5.2.9 Clean the electric panels with dry lint free cloth.
- 5.2.10 Wipe the all parts with 70 % v/v IPA solution.
- 5.2.11 In case equipment remains idle for 72 hours, re-clean the equipment by wiping with 70 % v/v IPA solution before use.
- 5.2.12 Affix duly filled and signed “CLEANED” label on the equipment.
- 5.2.13 Record the cleaning completion time in the equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).
- 5.2.14 **Frequency**
 - 5.2.14.1 Type ‘A’ cleaning is applicable after completion of every batch of same product. If same product is processed for more than a week then follow the procedure of type – B cleaning.
 - 5.2.14.2 Type ‘B’ cleaning is applicable in case of changeover of product with different actives / colour / descending potency or after maintenance of contact parts or same product is run for more than



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

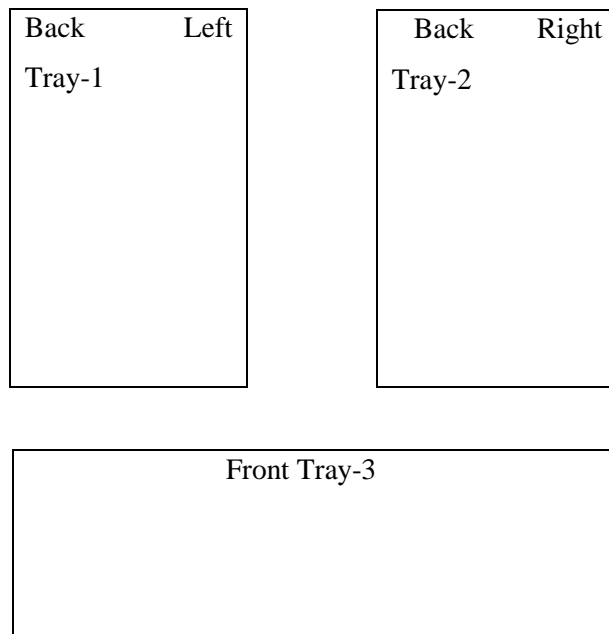
Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

seven days cleaning Type - B done after completion of batch.

NOTE: After Type - B cleaning, if machine is not used within 72 hours, clean the machine “before use”, with the lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and dully sign the “CLEANED” label again. Record the activity in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.3 **SETTING OF MACHINE:**

- 5.3.1 Set the temperatures as per the instruction given in the respective BMR, wait till the tray dryer attains required temperature.
- 5.3.2 Take the tray from VTD, Put the tray on SS pallet and pour the material in to tray with help of SS jug as per respective BMR instruction or about 1-3 liter (Approximately 1-3 kg) material in each tray and spread the material uniformly for quick drying.
- 5.3.3 After material loading insert the filled tray in to VTD starting to stack them From bottom to top and left to right sequence in following manner.



- 5.3.4 The numbering is allotted from Left back is no 1; right back is no.2 and front is no.3.This sequences for numbering and loading is following for rest of trays.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.4 EQUIPMENT OPERATION

5.4.1 VTD MILLANIUM

5.4.1.1 Ensure "CLEANED" label duly filled and signed is affixed on the equipment. Ensure cleanliness of equipment and area. Remove the "CLEANED" label and affix it in the respective BMR. Affix "Equipment status" label duly filled and signed on the equipment and record all the observations in the equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").

5.4.1.2 Arrange the trays with the material as describe in the Setting of Machine.

5.4.1.3 Lock the door of Vacuum Tray Dryer.

5.4.1.4 Open all the valve lines.

5.4.1.5 Close vacuum release valve.

5.4.1.6 Ensure that water line is open that supplies water to vacuum pump.

5.4.1.7 Start vacuum pump by pressing 'GREEN' push button.

5.4.1.8 Racking done if required by following procedure.

5.4.1.9 Close the isolating valve between condenser and receiver.

5.4.1.10 Stop the flow of heating media in dryer.

5.4.1.11 Switch 'OFF' the vacuum pump by pressing 'RED' push button.

5.4.1.12 Open the vacuum release valve.

5.4.1.13 Open the door and remove the tray.

5.4.1.14 Put the tray on SS pallet and rack the material gently with help of SS scoop/SS spatula one by one and keep the tray in to VTD on its respective allotted place.

5.4.1.15 Repeat steps 5.4.1.2 to 5.4.1.13 to restart the process.

5.4.1.16 Sampling done if required by following procedure.

5.4.2 VTD S2 ENGINEERING:

5.4.2.1 Ensure "CLEANED" label duly filled and signed is affixed on the equipment. Ensure cleanliness of equipment and area. Remove the "CLEANED" label and affix it in the respective BMR. Affix "Equipment status" label duly filled and signed on the equipment and record all the observations in the equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").

5.4.2.2 Arrange the trays with the material as describe in the Setting of Machine.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.4.2.3 Lock the door of Vacuum Tray Dryer.
- 5.4.2.4 Open all the valve lines.
- 5.4.2.5 Close vacuum release valve.
- 5.4.2.6 To start the machine switch ON the knob presented on the PLC panel.
- 5.4.2.7 Vacuum to be starts by PRESS on the knob.
- 5.4.2.8 For inlet setting at PLC Press the Star “☼” button
- 5.4.2.9 Set the required temperature as per BMR Press the Button ▲ to increase and ▼ to decrease the set temperature.
- 5.4.2.10 The vacuum display on the lower side of the PLC.
- 5.4.2.11 Racking done if required by following procedure.
- 5.4.2.12 Close the isolating valve between condenser and receiver.
- 5.4.2.13 Stop the flow of heating media in dryer.
- 5.4.2.14 Open the vacuum release valve.
- 5.4.2.15 Open the VDT door.
- 5.4.2.16 Take the sample as per respective individual sampling protocol / respective BMR instruction / SOP (“In process sampling”).
- 5.4.2.17 Repeat steps 5.4.2.2 to 5.4.2.15 to restart the process.
- 5.4.2.18 After the operation is over, close the isolating valve between condenser and receiver.
- 5.4.2.19 Stop the flow of heating media in dryer.
- 5.4.2.20 Switch ‘OFF’ the vacuum pump by pressing ‘RED’ push button.
- 5.4.2.21 Open the vacuum release valve.
- 5.4.2.22 Open the door of VTD.
- 5.4.2.23 Unload the material after process completed in to respective IPCs/Bin with the help of SS scoop / SS spatula.
- 5.4.2.24 Remove and destroy “EQUIPMENT STATUS” label.
- 5.4.2.25 Affix “UNDER CLEANING” labels duly filled and signed on the equipment.
- 5.4.2.26 Record all the observations in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Vacuum Tray Dryer

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

6.0 ABBREVIATION (S):

- 6.1 IPA : Iso Propyl Alcohol
- 6.2 SOP : Standard Operating Procedure
- 6.3 No. : Number
- 6.4 v/v : Volume/Volume
- 6.5 BMR : Batch Manufacturing Record
- 6.6 QA : Quality Assurance
- 6.7 IPC's : In process containers

7.0 REFERENCE (S):

- 7.1 SOP: Making entries in equipment usage and cleaning log sheet.
- 7.2 SOP: In process sampling

8.0 ANNEXURE (S):

Annexure No.	Title of Annexure	Format No.	Mode of Execution
Annexure – I	Equipment cleaning checklist		Logbook

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled copy (s)** : Production department (01), Quality Assurance (01)
- 9.3 **Reference copy (s)** : Production department (02)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of revision	Effective Date
01	00	NA	New SOP	NA	NA



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I

Equipment Cleaning Checklist (20 Station)

Name of the Equipment		COMPRESSION MACHINE (20 STATION)	
Equipment I.D. No.		Previous product	
Batch No.		Date	

S.No.	Activity	Activity performed
1.	Unscrew the panel covering on the front side and the side covers.	
2.	Dry clean the machine control panel with dry lint free cloth.	
3.	Clean beneath the compression machine and fit the panel covering back in place.	
4.	Dismantle the feed hopper, feed frame, upper punch safety rail and feeder base.	
5.	Dismantle the scrapper blade, ejection plate, & Put all the dismantled parts in a virgin polybag affixed with "TO BE CLEANED" label and transfer the poly bag to respective cleaning area.	
6.	Clean all the above parts first with 10-15 liters of purified water, then clean by using nylon scrubber and wash with 20 – 30 liters of purified water.	
7.	Finally rinse all the above washed parts with 15-20 liters of purified water.	
8.	Wipe all the cleaned parts with lint free cloth dipped in 70%v/v IPA.	
9.	Dry all the parts using a dry lint free cloth.	
10.	Open the acrylic guards of machine and clean with a dry lint free cloth followed by lint free cloth dipped in 70 % v/v IPA.	
11.	Remove the upper punches one by one and clean with a lint free cloth and keep in a trolley.	
12.	Remove anti- turning plugs and tension plate.	
13.	Remove the plug by turning the nuts into anticlockwise direction.	
14.	Remove the lower punches through the hole one by one, wipe to clean and keep in a SS trolley.	
15.	Remove the adhered powder from the lower punch barrels with dry lint free cloth and bottom of dies with a nylon brush.	
16.	Clean the upper punch pocket using a dry nylon brush first and then clean with a nylon brush dipped in 70% v/v IPA and dry the punch pocket using a cleaned lint free cloth.	
17.	Unscrew the die locks and insert the small S.S. bar in lower punch bore to remove it out.	
18.	Remove all the dies and keep in a SS trolley.	



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vacuum Tray Dryer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

S.No.	Activity	Activity performed
19.	Clean the die bore with nylon brush dipped in 70% v/v IPA and dry with a cleaned lint free cloth.	
20.	Remove the upper and lower cam tracks and clean it with a lint free cloth dipped in 70% v/v IPA	
21.	Clean the turret with a dry lint free cloth followed by lint free cloth dipped in 70 % v/v IPA.	
22.	Transfer the dust extractor pipes to the washing area in a polythene bag and wash the inside of the pipes under a flow of purified water. Wipe the outside of the pipes of the dust extractor with a lint free cloth dipped in purified water.	
23.	Dry the pipes with the help of compressed air.	
24.	Fit the side covers of the compression machine back in place.	
25.	Keep all the dried parts on a cleaned stainless steel pallet and cover it with a virgin polythene bag or shrink wrap with a status label as "CLEANED" with date and signature of the production officer and transfer them to respective compression area.	

Note: Put '√' mark if activity is performed and put 'X' if activity is not performed.

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date